



Appendices





Agenda

National Institute of General Medical Sciences
Indian Health Service
American Indian Research Training Needs Meeting
Natcher Conference Center
Conference Room 31/E2
August 23-24, 2000

August 23, 1999-8:30 am

Traditional: Richard Harrison, NIDA
Welcome: Ruth Kirschstein, MD,
Deputy Director, NIH

Introduction: JoAnn Kauffman
Presenters: Clifton Poodry, Leo Nolan

Issues of Credibility with American Indian Community

Presenter: Lillian Tom-Orme
Discussants: Linda Burhansstipanov
Marlene Jasperse
Open Discussion

Needs of New Basic Science Investigators

Presenter: John Gilber
Discussants: Wilfred Denetclaw, David Burgess
Open Discussion

MD/Professionals Who Want to Do Research

Presenter: Yvette Roubideaux
Discussant: Judith Kaur, Jeffrey Henderson
Open Discussion

Lunch

Encouraging/Engaging Students– What Has Worked?

Presenters: Clifton Poodry
IMSD udit Camacho-SACNAS
James Jarvis
*Headlands Spero Manson–
U. of Colorado*
Sandra Begay-
Campbell-AISES

Discussants: Judith Gobert and Sophia Cleland
Open Discussion

Instructions for Breakout

Presenter: JoAnn Kauffman

Discussion of Recommendations– Breakout Work Groups

Reception Conference Room G–4:30 pm

August 24, 1999-8:30 am

Discussion of Recommendation– Breakout Work Groups (continued)

Report Back–11:00 am

Summary: Yvette Roubideaux

Next Steps: Clifton Poodry, Michael R. Martin
and Leo Nolan



DHHS Tribal Consultation Policy





The Secretary of Health and Human Services

Washington, D.C. 20201

September 19, 1997

Dear Tribal Leader:

I am pleased to provide you the enclosed copy of the Department of Health and Human Services' (HHS) "Policy on Consultation with American Indian and Alaska Native Tribes and Indian Organizations," which was issued on August 7, 1997. We are proud of the relationship between our Department and the Native American community and hope that this new policy will further strengthen that relationship.

As you may know, President Clinton issued an Executive Memorandum to federal departments and agencies entitled, "Government-to-Government Relations with Native American Tribal Governments." The President's Memorandum reaffirmed the unique relationship between the U.S. government and tribal governments and directed each federal department and agency to honor this relationship by consulting with tribal governments before taking actions that affect them.

To ensure that our Department appropriately implemented this directive, we established a working group to examine how HHS could better consult with Native Americans on the development of HHS policies and programs. Former Principal Deputy Assistant Secretary for Health Jo Ivey Bufford, M.D., and Indian Health Service Director Michael Trujillo, M.D., co-chaired this effort. Early on, the working group met with tribal representatives to discuss consultation requirements. We are grateful for the valuable contributions that these leaders made during the development of our Department's consultation policy.

As indicated in the enclosed document, our Department's policy requires each HHS agency to develop a tribal consultation plan. In addition, HHS is to conduct Department-wide consultations as necessary. I invite you and other tribal leaders to provide further comments on our policy, so that we may build a more effective consultation process in the future.

I have designated the Office of Intergovernmental Affairs (IGA) as the lead office for tribal consultation within HHS. Located in the Immediate Office of the Secretary, IGA has served as the Department's liaison to state and local governments and will now also provide similar focus and leadership for tribal matters. Ms. Katie Steele is the Acting Director of

that office and can be reached on (202) 690-6060. Ms. Steele is currently recruiting HHS staff to oversee our Department's tribal consultation and outreach functions. We are pleased to announce that Ms. Bea Bowman, currently the Director of the Division of Community Services in our Indian Health Service, will shortly join IGA as senior advisor on tribal issues. Should you have any questions or concerns about HHS programs, please do not hesitate to contact Ms. Steele.

In the meantime, I hope the enclosed policy proves helpful to you. We look forward to working with you and other tribal leaders in strengthening the government-to-government relationship and our joint efforts to improve the health and well-being of our Nation's Native American citizens.

Sincerely,



Donna E. Shalala



Department of Health and Human Services Working Group Report on Consultation with American Indians and Alaska Natives Report

Summary and Recommendations

Introduction

The Domestic Policy Council (DPC) Working Group on Indian Affairs chaired by Secretary Babbitt has requested that each department develop its own operational definition of "consultation" with Indian tribes to meet the requirements of both the Indian Self-Determination and Educational Assistance Act, Public Law (P.L.) 93-638, and the April 29, 1994, Executive Memorandum on Government-to-Government Relations with Native American Tribal Governments. Each department should also develop mechanisms to ensure that Native American tribal governments are given an opportunity to provide input on department plans and that the approach decided upon is clearly communicated to Indian communities.

The United States (U.S.) government and the governments of American Indians and Alaska Natives (AI/AN or Indian people) have a "government-to-government" relationship based on the U.S. Constitution, treaties, Federal statutes, court decisions, and Executive Branch policies, as well as moral and ethical considerations. This special relationship also constitutes a trust relationship between these two governments. Certain benefits provided to Indian people through Federal legislatively enacted programs flow from this trust relationship. These benefits are not based upon race, but rather, are derived from the government-to-

government relationship. A vital component of this relationship is consultation between the Federal and tribal governments. In cases where the government-to-government relationship does not exist, as with urban Indian centers, Inter-tribal organizations, state recognized tribal groups, and other Indian organizations, consultation is encouraged to the extent that there is not a conflict-of-interest in the above stated Federal statutes or the Operating Division/Staff Division (OPDIV/STAFFDIV) authorizing legislation. Some aspects of this consultation are set out in statute and administrative policy.

Foundations

Federally Recognized Tribes

The special relationship between the U.S. government and tribal governments is grounded in many historical, political, legal, moral, and ethical considerations. Increasingly this special relationship has emphasized self-determination for Indian people and meaningful involvement by Indian people in Federal decision making (consultation) where such decisions affect Indian people, either because of their status as Indian people or otherwise.

Consultation examples include:

1. A provision in the Indian Self-Determination and Education Assistance Act, P.L. 93-638, as amended, codified at 25 U.S.C. 450a states that:

- Congress...recognizes the obligation of the United States to respond to the strong expression of the Indian people for self-determination by assuring maximum Indian participation in the direction of...Federal services to Indian communities so as to render such services more responsive to the needs and desires of those communities."

- The Congress declares its commitment to the maintenance of the Federal government's unique and continuing relationship with, and responsibility to, individual Indian tribes and Indian people as a whole through...effective and meaningful participation by the Indian people in the planning, conduct, and administration of those programs and services.

2. Regulations implementing the Indian Self-Determination Act, as amended, contain the following provisions:

- 25 C.F.R. 900.3 (a) (2): "Congress has declared its commitment to the maintenance of the Federal government's unique and continuing relationship with, and responsibility to, individual Indian tribes and to the Indian people as a whole through the establishment of meaningful Indian self-determination policy which will permit an orderly transition from the Federal domination of programs for, and services to, Indian s to effective and meaningful participation by the Indian people in the planning, conduct and administration of those programs and services."
- 25 C.F.R. 900.3 (b) (1): "It is the policy of the Secretary to facilitate the effort of Indian tribes and tribal organizations to plan, conduct,

and administer programs, functions, services and activities, or portions thereof, which the departments are authorized to administer for the benefit of Indians because of their status as Indians...."

3. The Indian Health Care Improvement Act, P.L. 94-437, contains a "Congressional Finding," codified at 25 U.S.C. 1601, that:

- A major national goal of the United States is to provide the quantity and quality of health services which will permit the health status of Indians to be raised to the highest possible level and to encourage the maximum participation of Indians in the planning and management of those services."

4. The unfunded Mandates Reform Act of 1995, P.L. 104-4 states:

- Section 2. "The purposes of this Act are...to assist Federal agencies in their consideration of proposed regulations affecting...Tribal governments by...requiring that Federal agencies develop a process to enable...Tribal governments to provide input when Federal agencies are developing regulations, and requiring that Federal agencies prepare and consider the budgetary impact of Federal regulations containing Federal mandates upon...Tribal governments before adopting such regulations."

5. The President's Memorandum of April 29, 1994, to heads of executive departments and agencies titled, "Government-to-Government Relations with Native American Tribal Governments," outlines the concepts of consultation.

*Non Federally Recognized Tribes and
Other Native American People*

Indian people are often significantly or differentially affected by the Department of Health and Human Services (HHS) actions, may have special needs that HHS policy makers may not be sensitive to, may make especially valuable contributions to policy formulation and program administration because of their unique perspectives, and may be expressly mentioned in HHS statutes, or need to be effectively and efficiently served as a part of the HHS' mission.

Although the special "tribal-federal" relationship is based in part on the government-to-government relationship, other statutes and policies exist that allow for consultation with non-federally recognized tribes and other Indian organizations that, by the mere nature of their business, serve Indian people and might be negatively affected if excluded from the consultation process. Specifically:

- A statute administered by the Indian Health Service (IHS), 25 U.S.C. 1653, requires the Secretary of HHS to enter into contracts with or issue grants to urban Indian organizations to assist such urban centers for the provision of health care and referral services for urban Indians residing in the urban centers in which such organizations are situated. (42 U.S.C. 1654 authorizes grants and contracts with urban Indian organizations to determine the health status and unmet health needs of urban Indians.)
- A statute administered by the Administration for Native Americans (ANA), Sec. 802. [42 U.S.C. 2991b], provides financial assistance for Native American projects including but not limited to, governing bodies of Indian tribes on Federal and State reservations, Alaska Native villages and

regional corporations established by the Alaska Native Claims Settlement Act, and such public and nonprofit agencies serving Native Hawaiian, and Indian and Alaska Native organizations in urban and rural areas that are not Indian reservations or Alaska Native villages, for projects pertaining to the purposes of this title. The Commissioner is authorized to provide financial assistance to public and nonprofit private agencies serving other Native American Pacific Islanders (including American Samoan Natives) for projects pertaining to the purposes of this act. In determining the projects to be assisted under this title, the Commissioner shall consult with other Federal agencies for the purposes of eliminating duplication or conflict among similar activities or projects and for the purpose of determining whether the findings resulting from those projects may be incorporated into one or more programs for which those agencies are responsible. Every determination made with respect to a request for financial assistance under this section shall be made without regard to whether the agency making such request serves, or the project to be assisted is for the benefit of, Indians who are not members of a federally recognized tribe.... The statute (42 U.S.C. 2991b-2 (c) (2) also requires that the Administration for Native Americans (ANA) Commissioner, "serve as an effective and visible advocate for Native Americans....;" while 42 U.S.C. 2991b-2 (d) establishes, in the Office of the Secretary, the Intra-Departmental Council on Native American Affairs. Among its responsibilities, 42 U.S.C. 2991b-2 (c) (3) requires that this council assist the Commissioner in "coordinating activities within the department leading to the development of policies, programs, and budgets, and their administration that directly affect Indian and other Native populations"

- A statute administered by the Administration for Children and Families that establishes the Low Income Home Energy Assistance Program (42 U.S.C. 8621 et seq.) and its implementing regulations (45 C.F.R. 96.48) make clear that Federal and State recognized tribes may receive direct funding under this block grant.
 - A Statute administered by the Health Resources and Services Administration that establishes the Centers of Excellence in the Minority Health Program (42 U.S.C. 293c (c) (4), (d) (3), (e) provides for the funding of programs in health professions education at Native American Centers of Excellence.
- Other HHS components that rely on more general statutory consultation language conduct activities that directly affect Indian people.
- The Domestic Policy Council (DPC)
Working Group on American Indian/Alaska
Native Affairs Consultation Process*
- In response to the President's 1994 Memorandum, the DPC's Working Group on Indian Affairs led by the Secretary of the Interior established a subgroup to develop a consultation policy. After nearly 2 years of analysis and deliberations toward devising a uniform, Government-wide consultation policy, the DPC concluded that such uniformity was undesirable given the different organizational structures, statutory considerations and administrative processes between Federal departments and agencies. Therefore, the DPC recommended that each department be charged with developing its own individualized consultation policy/plan. The DPC drafted guidelines identifying six points that should be addressed by each department's consultation policy/plan:
- Each department will develop a general department-wide AI/AN policy/plan that outlines its general direction on consultation.
 - Each department will develop its own methods of consultation based on its internal requirements using tools that it has available.
 - As part of the decision-making process for major issues that affect AI/Ans, each department will develop a short "consultation plan" that will indicate to tribal governments how, for example, consultation in general, and time frames would be carried out on a particular issue.
 - Each department will include an appropriate plan for the receipt of input, allowing for adequate response time, on AI/AN appropriation needs before the department submits its fiscal budget to the Office of Management and Budget. Each department should encourage tribal government input in its budget formulation process so that it may be useful to their decision-making.
 - Each department will utilize either the Codetalk Home Page or its own Home Page (with a link to Codetalk) to make its consultation plan known to the tribes and the public. Each department should also use its Home Page to solicit tribal government comments on its consultation plan. Finally, each department should have its own American Indian/Alaska Native Policy statement available at the same Home Page source.
 - Each "consultation plan" should include sufficient time and access so that tribes may provide input before a final decision is made.

HHS AI/AN Consultation Processes and Recommendations

The DPC's recommendations on departmental policy formulation led to the creation of an HHS Working Group on Consultations with American Indians and Alaska Natives. Co-chaired by Jo Ivey Boufford, MD, former Acting Assistant Secretary for Health, and Michael H. Trujillo, MD, Director, Indian Health Service (IHS). This group is comprised of representatives from the department's major Operating Divisions and Office of the Secretary Staff Divisions (OPDIV/STAFFDIV). During several meetings, the group explored the broad array of AI/AN programs within the department that resulted in a departmental report, "Improving the Health and Well-Being of American Indians and Alaska Natives." This report is a summary of each OPDIV/STAFFDIV's 1995-1996 activities and/or programs for AI/AN people.

The HHS Working Group also reviewed each OPDIV/STAFFDIV's current approach(es) to consultation, and worked to develop recommendations for a departmental approach to consultation that could be forwarded to the Secretary. The working group recommended that the department's Consultation Plan consist of the individual OPDIV/STAFFDIV plans and any department-wide consultation processes as deemed necessary.

Recommendations

HHS Approach to Consultation

Based on the HHS Working Group deliberations and review of work accomplished by IHS, the following definition of "consultation" is proposed for HHS use:

- "Consultation is an enhanced form of communication which emphasizes trust, respect and shared responsibility. It is an open and free exchange of information and opinion among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process which results in effective collaboration and informed decision making."

It is recommended that the policy of this Department be:

- To consult with Indian people to the greatest practicable extent and to the extent permitted by law before taking actions that effect these governments and people;
- To assist States in the development and implementation of mechanisms for consultation with their respective tribal governments and Indian organizations before taking actions that affect these governments and/or the Indian people residing within their state. Consultation should be conducted in a meaningful manner that is consistent with the definition of "consultation" as defined in this policy, including reporting to the appropriate HHS agency on its findings, and on the results of the consultation process that was utilized;
- To assess the impact of this Department's plans, projects, programs and activities on tribal and other available resources;
- To remove any procedural impediments to working directly with tribal governments or Indian people; and
- To work collaboratively with other Federal agencies in these efforts.

Departmental-Level Actions

Consistent with the thrust of the DPC guidance on budget consultation, it is recommended that the Office of Intergovernmental Affairs (IGA), IHS, ANA, and the Office of Minority Health (OMH), convene for the department, an annual meeting of Indian people to present their appropriation needs and priorities. The OPDIVs and STAFFDIVs are encouraged to suggest participants that should be included in attendance. This meeting should take place before the submission by OPDIVs/STAFFDIVs of their budget requests to the department (probably in May of each year). The Assistant Secretary for Management and Budget and other appropriate OPDIVs/STAFFDIVs will have representatives at this meeting to ensure that these needs and priorities are made known to the members of the department's Budget Review Board.

Before the annual meeting, a brief, clear document summarizing the preceding year's departmental budget should be made available as a basis for discussion to all potential consultation participants. Before or after this meeting, OPDIVs/STAFFDIVs who wish to conduct consultation on the fiscal year budgets specific to their programs or other OPDIV/STAFFDIV activities relevant to AI/AN, are encouraged to do so (the proposed approach should be outlined in the specific OPDIV/STAFFDIV consultation policy/plan).

The department should determine if there are other issues or priorities for legislation or cross cutting initiatives that require department level consultation and develop a process for such consultation, otherwise, the processes developed by each OPDIV/STAFFDIV should be aggregated as the departmental process and communicated appropriately.

The department will designate a single point-of-contact that can provide AI/AN representatives with access to departmental program information and assistance. This function will be located in the OS/IGA, linked to HHS Regional Offices for field follow-up/contact.

OPDIV/STAFFDIV Level Actions

Recommendations

Each OPDIV should prepare a draft policy/plan for a consultation process. The OS should be considered an OPDIV for these purposes so that STAFFDIVs may consult as a group and develop an integrated, cross-cutting consultation process. This draft will be reviewed by the Working Group for comment and by the Office of the General Counsel for any legal issues. The Assistant Secretary for Management and Budget would be considered the lead for the annual Department-wide budget consultation described above.

Each OPDIV (and STAFFDIV) should consult with AI/AN leaders on their "reviewed" policy/plan (see IHIS "Tribal Consultation and Participation Policy," (Attachment A).

Each OPDIV (and STAFFDIV) policy/plan should include:

- A specific delineation of the issues on which advice/consultation will be sought or criteria that will be used to identify the issues. In general, budget matters and legislation affecting tribes are considered critical for consultation. The OPDIVs/STAFFDIVs which have difficulty with this item may wish to conduct a focus group of AI/AN representatives to recommend the kinds of items on which consultation should be conducted.
- A provision that seeks to ensure that the

OPDIV/STAFFDIV will assist States in the development and implementation of mechanisms for consultation with their respective tribal governments and Indian organizations before taking actions that affect these governments and/or the Indian people residing within their State. Consultation should be conducted in a meaningful manner that is consistent with the definition of “consultation” as defined in this policy, including reporting to the appropriate HHS agency on its findings, and on the results of the consultation process that was used.

- A mechanism by which the OPDIV/STAFFDIV will evaluate the States efforts in compliance with the consultation process with tribal governments and Indian organizations.
- Guidelines that define how the OPDIV/STAFFDIV will address States in situations where the evaluation has identified deficiencies in the consultation process as set forth in this policy.
- A defined process for early inclusion of tribal governments and other Indian people in the decision-making process;
- Specific mechanisms that will be used to consult with tribal governments. In consultation with tribal governments and other Indian people, the decision could be made to use IHS or other mechanisms such as intermediate national or regional organizations and conferences, or establish specific structures for ongoing advice from Indian communities.

Consultation process

Further, each OPDIVs/STAFFDIVs plan should also provide:

- Sufficient background information to assure a thorough understanding of each issue on which consultation is requested, including a clear statement of the potential impact of the proposed action on Indian people.
- A clear statement of the advice requested.
- A specific time frame for response from consulted entities.
- A clear indication of who should receive the reply.

Upon completion of consultation, there may be issues that would benefit from ongoing involvement of Indian people in implementation and evaluation. The OPDIV/STAFFDIV plans should include mechanisms to address this need.

Timely feedback should be provided to Tribes and Indian organizations on the resolution of the issue for which consultation was requested.

The consultation process when finalized should be displayed on the OPDIV/STAFFDIV's Home Page and on OMH's Association of American Indian Physicians (AAIP) Home Page, which already connects to the IHS Home Page and should be connected to the HHS and Codetalk Home Pages. It was noted that assuring adequate consultation may require the investment of resources by the OPDIVs/STAFFDIVs, such as

provision of training, detailing of staff or providing information technology to tribal governments and other Indian people. In instances where computer capabilities are absent, OPDIVs/STAFFDIVs should attempt to disseminate information by other media mechanisms such as the telephone, newspaper, magazines, newsletters, etc.

Establishment of a single point-of-contact for tribal governments and other Indian people within each OPDIV/STAFFDIV at a level with access to information of all the OPDIVs/STAFFDIVs operating components and programmatic levels is recommended. This will assist the department's point of contact in the IGA in accessing department-wide information and aid in providing a single entry point to HHS-wide information.

Each OPDIV/STAFFDIV will submit to the IGA by December 31 an annual report on the previous fiscal years consultation activities addressing how each point in their plan was implemented for each consultation conducted.

Summary

We have endeavored to consider a wide range of OPDIV/STAFFDIV needs and unique characteristics in crafting these guidelines. As there is variability among the OPDIVs/STAFFDIVs, there is also a need to allow for variability over time. Hence, it is important that consultation plans developed by OPDIVs/STAFFDIVs remain dynamic, changing as circumstances and AI/AN input indicate. Once the Department has its basic consultation policy in place, it should seek to integrate its efforts with those of other departments and agencies. Such intra-governmental coordination will benefit the departments and agencies as well as AI/Ans.



Navajo Nation Research Program–
Institutional Review Board Application





Navajo Division of Health/Navajo Research Program

Navajo Health Research Review Board

IRB Application

Date: _____

Project title: _____

Manuscript title: _____

Name of Principle Investigator (PI)/Author: _____

Title/Affiliation of the PI/Author: _____

Address: _____

City/State: _____ Zip: _____

Phone: _____

Fax: _____

E-mail: _____

Official Use Only

Application Received: _____

Progress Report Received:

IRB Approval Date: _____

1st qtr _____

Proposal ID#: NNR- _____ - _____

2nd qtr _____

Manuscript ID#: NNR- _____ - _____

3rd qtr _____

IHS IRB Action Letter: _____

4th qtr _____

Continuation Report: _____

Research Final Report: _____



Navajo Division of Health/Navajo Research Program

Navajo Health Research Review Board

IRB Application

Guidelines

The general guidelines for submitting the IRB applications for review of your research proposal and/or manuscript are as follows:

1. The proposal must be submitted to the Navajo Nation Research Program to:

Marlene. L. Jasperse, PhD, Division Director
Attn: Joquetta DeGroat
Navajo Division of Health
Office of Planning, Research and Evaluation
Navajo Research Program
Window Rock Blvd. Admin. Bldg.#2
P.O.Box 1390
Window Rock, Arizona 86515

(This address serves as both the post office address and the package delivery address)

2. The proposal must include all the necessary documents before it will be reviewed. Abstracts, CV, Support Letters, other approved IRB Letter(s), Certificate of Confidentiality (if needed), OMB Clearance document (if needed), a copy of the written letter to the Navajo Area IHS Director to abide by the Privacy Act (if needed), and the project budget.
3. For particularly sensitive projects/subject matter or if experimental drugs/devices are to be used in the project, the proposal/manuscript will be referred to an outside reviewer before the Navajo Nation Health Research Review Board reviews it.
4. If members of the San Juan Southern Palute Tribe, residing in the Tuba City and/or Kayenta Service Unit, are to be involved in the study and/or manuscript an approval of the San Juan Southern Palute Tribe is required.
5. The PI must submit twelve (12) copies in addition to the original proposal/manuscript to the Navajo Nation Health Research Review Board.



Principal Investigator(s)

The principal investigator must provide responses to all of the following questions on the IRB application. If an item does not apply to your particular proposal, state "Not applicable".

1. An abstract written in a simple clear language of your proposal research must be submitted to the Navajo Nation Research Program before proceeding with the IRB application.
2. A curriculum vitae or resume for the principal investigator(s) must be submitted as documentation to support the qualifications of the project staff to successfully conduct the proposed research.
3. A support letter/chapter resolution from at least one chapter house within the community of the research site must be obtained before the IRB process can proceed.
4. A support letter from the facility/ies where the research will take place must be obtained and be included in your research proposal before the IRB review process can proceed. If the research is going to be conducted at an IHS facility, a support letter from the CEO and the service unit health board must be obtained before the IRB review process can proceed. Likewise, if your research is going to be conducted at a school, a support letter from the school principal/superintendent and the area school board must be obtained before the IRB process can proceed.
5. A copy of the approval letter from another Institutional Review Board must be attached to your IRB application.
6. The Navajo Nation Health Research Review Board requests that the principal investigator(s) should apply for Certificate of Confidentiality from the National Institutes of Health to insure maximum protection for their study participants regarding their privacy.

7. If an investigator is a federal employee or is doing research under a contract or cooperative agreement and 10 or more people will be surveyed or given a questionnaire, clearance from the Office of Management and Budget (OMB) is required for research survey activities. Please contact Lance Hodakwen, coordinator for OMB clearance process for the Indian Health Service in Rockville, MD, at 301-443-0461, for information on clearance procedures.

8. All investigators, who are not federal employed and are reviewing and removing data from an IHS facility/ies, must write a statement, attesting to their understanding of and willingness to abide by the provisions of the Privacy Act to the Navajo Area IHS Director and the Navajo Area Office Privacy Act Coordinator. A copy of this letter must be attached to your IRB application.

9. A copy of the budget for your research project must be attached to the IRB application.

10. If your research involves collection of historic information, data, etc, then a permit from the Navajo Nation Historical Preservation Office may be required. You must contact the Navajo Nation Historical Preservation Office to secure a permit if necessary.

Research Project Description

11. Describe the background and rationale for your research project.
12. State the purpose, objectives, and/or hypotheses of your proposed research project.
13. Explain who is being recruited for the project. Indicate the number of participants to be recruited for your project.



14. Explain the procedures to be used for the participant recruitment, the selection criteria, and the exclusion criteria.

15. Describe the methods and the procedures for the study design, sampling, data gathering, data analysis, and plans for reporting the study results.

16. Describe the type and content of instruments to be used for data collection. Attach copies of the instruments to your IRB application.

17. Describe the contents and procedures to be used for the informed consent. Attach a copy of the informed consent to your IRB application. The consent should explain:

- The purpose of the research
- The expected duration of the subject's participation;
- The procedures to be followed, including the collection and testing of specimen, any reasonably foreseeable risks or discomforts to the participant
- Any benefits to the participant or others;
- The extent of which confidentiality of records identifying the participants will be maintained;
- An explanation of whom to contact for answers to questions about research and research participants rights;
- An explanation of whom to contact in the event of a research related injury to the participant, and;
- Participation is voluntary.
- The contact person for the Navajo Division of Health: Marlene L. Jasperse, PhD, Division Director at 520-871-6350

18. If you are going to collect any specimens (blood/tissue), explain precisely:

- What will you do with the specimens,
- What test(s) will you do;
- How long you will keep the specimens;
- How you will dispose of the specimens collected;
- How you will maintain anonymity of the specimens collected, and;
- Any other data that will be linked to each specimen collected in your research.

19. Explain the nature and procedures, if any, to be used for incentives for participation

20. Explain any potential physical or psychological risks or discomforts to participants that may be associated with or may result from your research project.

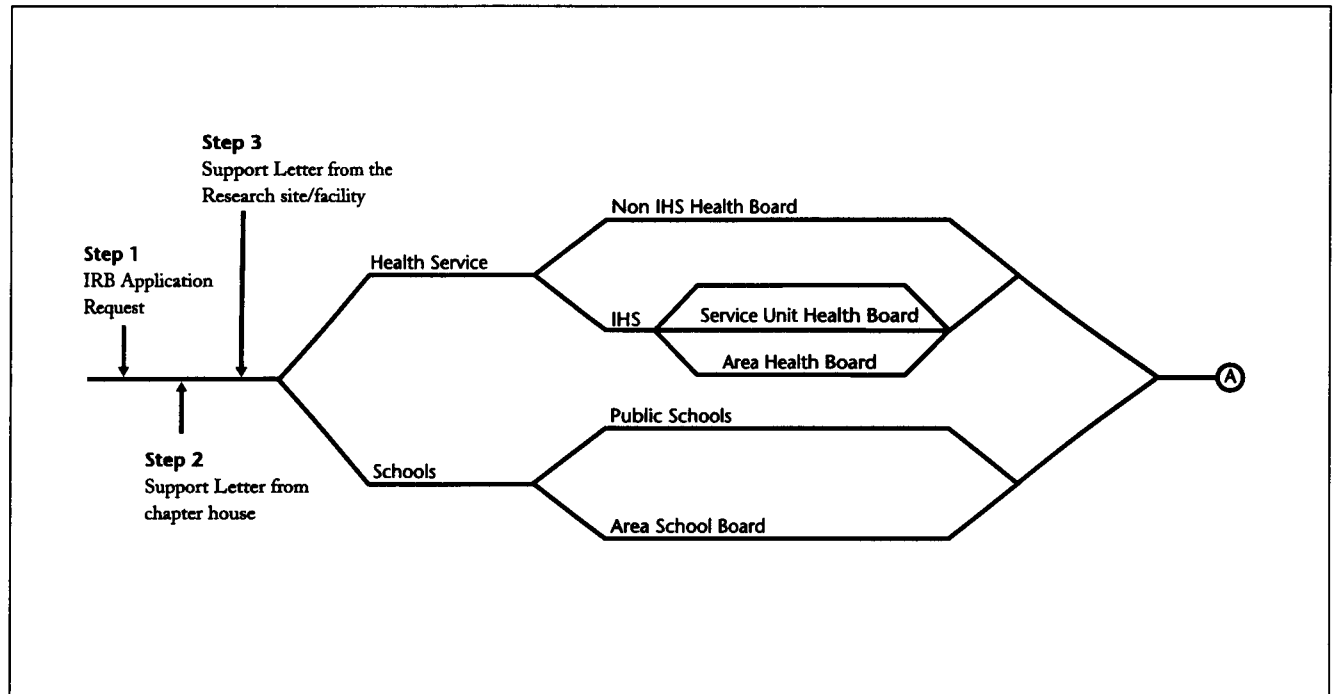
21. Indicate all locations where your project will be conducted.

22. Explain specifically how the results of your study will be used to improve the health status of the Navajo people.

23. Has this research been conducted elsewhere? If so, explain what were the results. Has it been conducted on the Navajo reservation? If so, explain what the results were. Or has it been coordinated with similar studies currently been conducted? If so, explain what plans will be made to insure that necessary coordination occurs and duplication is eliminated.

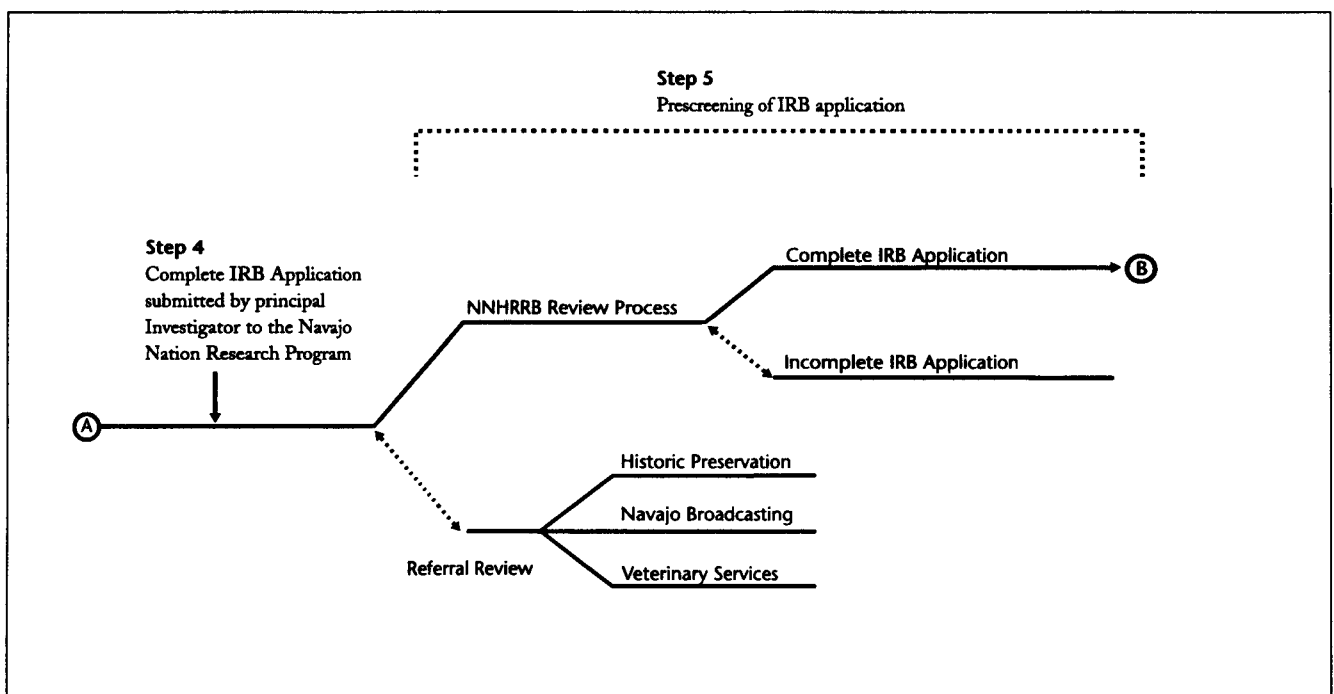
Pre-IRB Review Process

Phase 1 (Community Involvement)



Pre-IRB Review Process

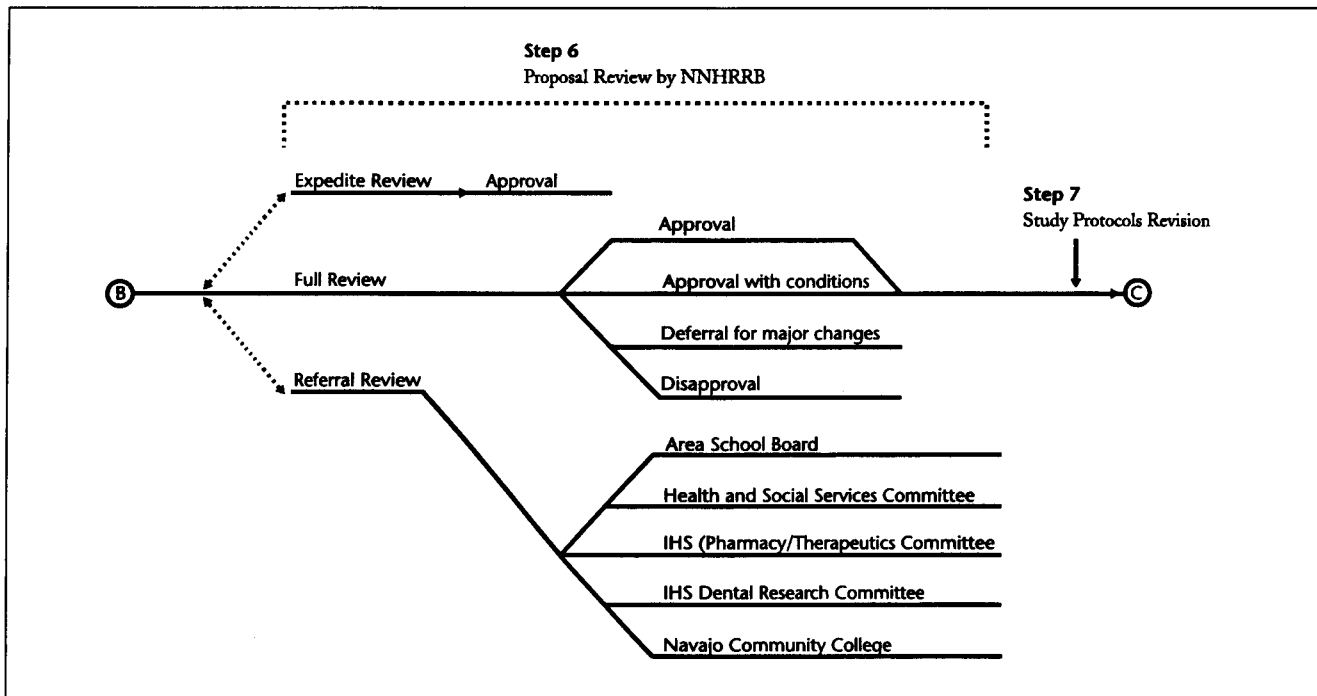
Phase 2 (Pre-screening)





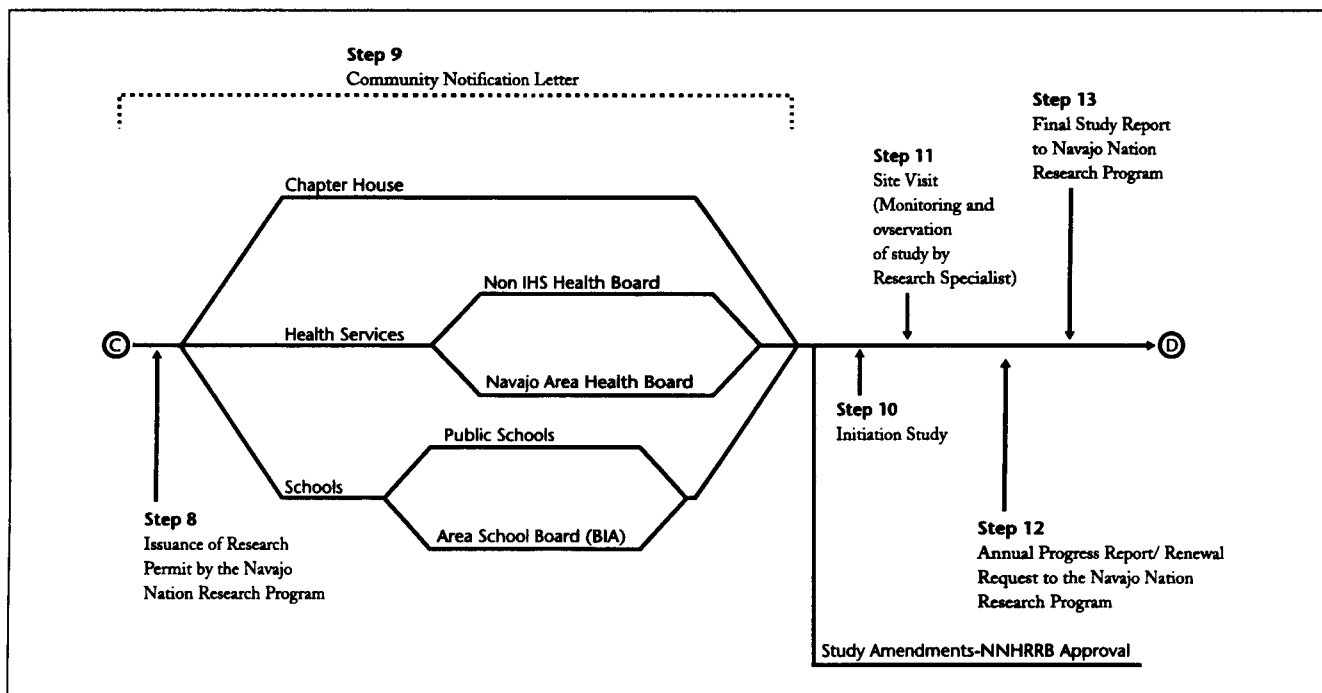
IRB Review Process

Phase 3 NNHRRB Review



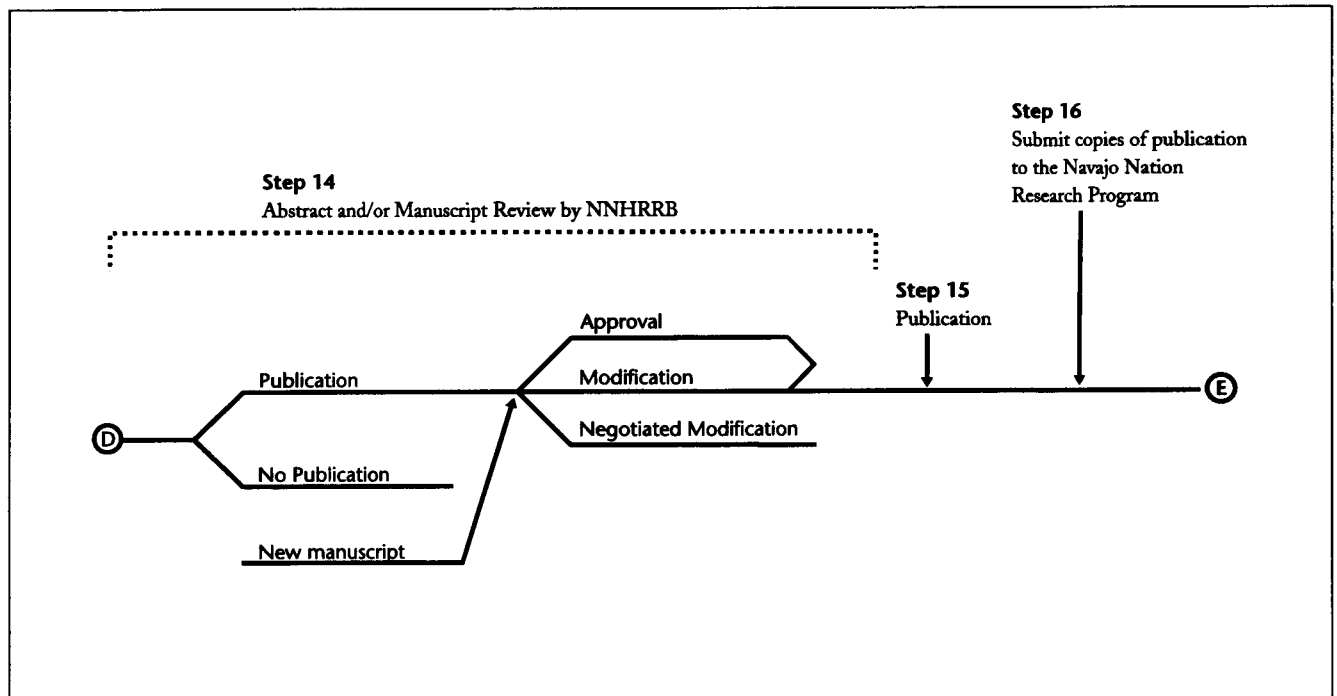
Post IRB Review Process

Phase 4 (Study)



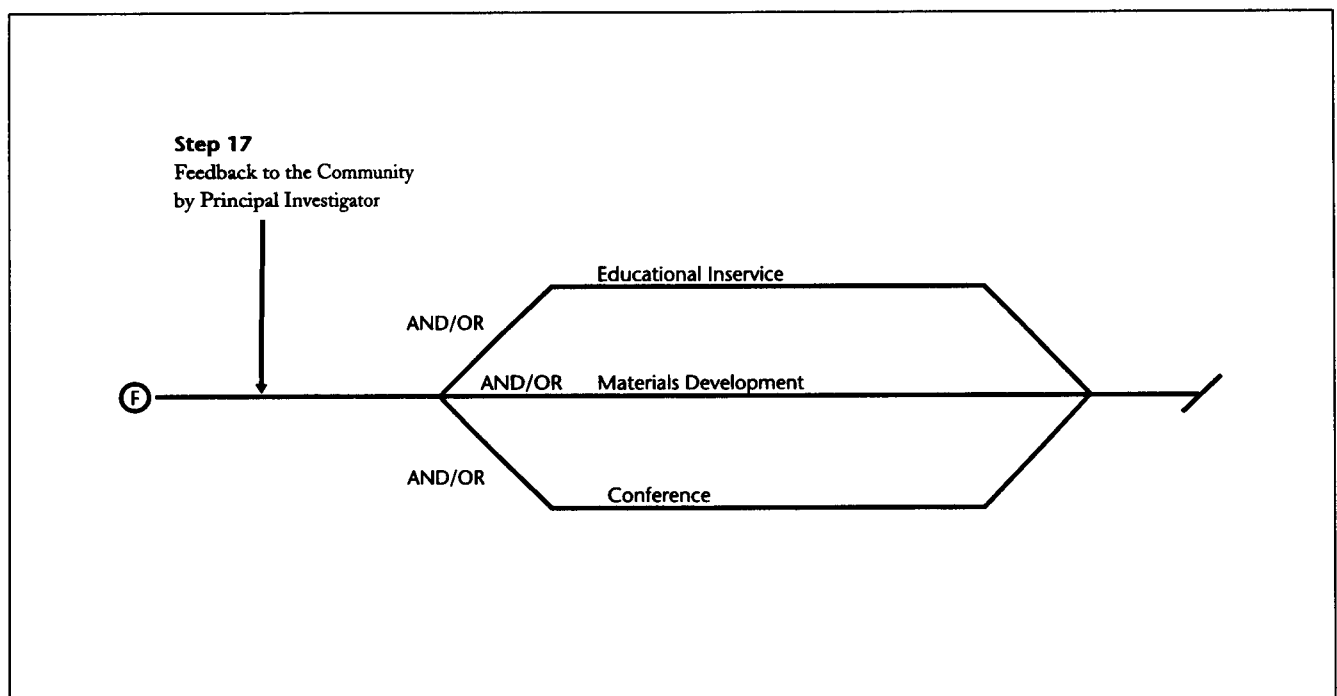
Post IRB Review Process

Phase 5 (Publication)



Post IRB Review Process

Phase 6 Feedback to the Community





Resolution of the Health and Social Service Committee Of the Navajo Nation Council

Accepting the Navajo Nation Health Research Code and Recommending Approval of the Navajo Health Research Code by the Navajo Nation Council.

Whereas:

1. Pursuant to 2 N.T.C. SS451 and 452 (b)(6), the Health and Social Services Committee of the Navajo Nation Council was established and continued as a standing committee of the Navajo Nation council with oversight authority over the Navajo Division of Health and Social Services; and
2. Pursuant to 2 N.T.C. S454 (B)(6), the Health and Social Services Committee of the Navajo Nation Council is authorized to recommend legislation relating to health, environmental health and social services; and
3. The primary responsibility of the Navajo Area Indian Health Services(IHS) Institutional Review Board/Publication Committee is to protect the rights and welfare of the human subjects recruited to participate in research activities and to protect communities in which research is conducted; and
4. The federal and state agencies lack knowledge of research clearance procedure established by the Navajo Nation and the Navajo Area IHS; and
5. In 1994, a total of 48 requests for research activities and 48 requests for 48 requests for manuscript publications were submitted to the Navajo Area IHS Institutional Review Board/Publication Committee for approval; and
6. In response to a directive of the Health and Social Service Committee of the Navajo Nation Council, the Navajo Division of Health, the Department of Justice and the Navajo Area IHS Institutional Review Board/Publication Committee developed a Navajo Nation Health Research Code; and
7. The Navajo Division of Health provided a comment period to each Division of the Navajo Nation Executive Branch, Office of the Speaker and Office of Chief Justice, beginning May 26,1995 and ending September 1, 1995 and it received 3 responses; and
8. The Navajo Division of Health supports the Navajo Nation having a primary authority regarding research activities within the jurisdiction of the Navajo Nation; and

9. The Health and Social Services Committee of the Navajo Nation Council has determined that the proposed Navajo Nation Health Research Code is in the best interest of the Navajo Nation. The proposed Navajo Nation Health Research Act is attached hereto and incorporated as Exhibit "A", to be codified within Title 13 of the Navajo Tribal Code.

Now therefore be it resolved that:

1. The Health and Social Services Committee of the Navajo Nation Council accepts the Navajo Nation Research Code which is attached and incorporated herein as exhibit "A".
2. The Health and Social Services Committee of the Navajo Nation Council recommends the Navajo Nation Council to approve the Navajo Nation Health Research Code, to be codified within Title 13 of the Navajo Tribal Code.

Certification

I hereby certify that the foregoing resolution was duly considered by the Health and Social Services Committee of the Navajo Nation Council at a duly called meeting at the Window Rock, Navajo Nation (Arizona), at which a quorum was present and that same was passed by vote of 4 in favor, 0 opposed and 0 abstained, this 10th day of October, 1995.



Vice Chairperson
Health and Social Services Committee

Motion: Marlene Thomas
Second: Jack Colorado



Exhibit "A"

Navajo Nation Health Research Code

1. Title

This Code shall be known as Navajo Nation Health Research Code.

2. Purpose

The purpose of this Code shall be to set forth the conditions under which investigators, physicians, researchers and others may perform health and health related research activities within the territorial jurisdiction of the Navajo Nation.

3. Policy

It is the policy of the Navajo Nation to ensure that all persons within the territorial jurisdiction of the Navajo Nation are free from unreasonably harmful, intrusive, ill-conceived or otherwise offensive research and investigation procedures.

4. The Health and Social Services Committee is authorized to promulgate rules and regulations consistent with and necessary to implement this Code.

5. Definitions

As used in this Code, the following definitions apply:

Subjects

As used in this Code, "Subjects" means a living individual about whom a researcher (whether professional or student) conducting research obtains private information or data through intervention or interaction with the individual, involving physical

procedures by which data are gathered (for example, venipuncture) and/or manipulations of the subject or the subject's environment.

Navajo Nation Health Review Board

This is the Board created in Section 5 of this Code.

Research

As used in this Code, "Research", is the use of systematic methods (including, but not limited to note taking, interviewing, video and audio taping) to gather and analyze information, for the purpose of proving or disproving a hypothesis, concepts or practices, or otherwise adding to knowledge and insight in a particular medical or psychological discipline. Generally, proposed studies are defined as "research" if their goal is to produce generalizable knowledge through the use of human subjects or volunteers whose protection must be assured in accordance with the ethical principals of respect for persons; the duty to help others or beneficence; and justice or fairness.

Publication

As used in this Code, the term "Publication" includes all proposed professional and program papers and reports concerning Navajo medicine and Navajo health care. Also requiring advance approval are papers based on research conducted within the territorial jurisdiction of the Navajo Nation, prepared for presentation at national or international professional society meetings be researchers. Papers or reports for technical and lay audience prepared and approved by Indian Health Service or the Navajo Nation for compliance with contract or grant requirements are specifically excluded from this definition.

Researcher

As used in this Code, the term “researcher” means any person, organization, business or other entity, which conducts research within the territorial jurisdiction of the Navajo Nation.

6. Creation of the Navajo Nation Health Research Review Board

There is hereby created the Navajo Nation Health Research Review Board, whose purpose is to review all the proposal for health and health related research which will occur within the territorial jurisdiction of the Navajo Nation, issue permits for those projects which are consistent with the terms and intent of this Code, and, as appropriate, review and approve the results of such studies before publication. Navajo Nation Health Research Review Board is administratively assigned to the Navajo Nation Division of Health for support services.

7. Composition and term of the Navajo Nation Health Research Review Board

The Navajo Nation Health Research Review Board shall be composed of 12 individuals, selected as follows: three (3) persons appointed by the Navajo Area Health Board; three (3) persons appointed by the office of the President of the Navajo Nation; three (3) persons appointed by the Health and Social Services Committee of the Navajo Nation Council; and three (3) persons appointed by the Navajo Area Indian Health Service Area Director. At least two persons serving on the Navajo Nation Health Research Review Board shall be licensed physicians. The term of an appointment to the Navajo Nation Health Research Review Board shall be three (3) years from appointment.

8. Meetings, Quorum

Navajo Nation Health Research Review Board shall meet at least quarterly, but as often as necessary. Seven members, one of who must be a licensed physician, of the Navajo Nation Health Research Review Board shall constitute a quorum.

9. Purpose of the Navajo Nation Health Research Review Board

The purpose of the Navajo Nation Health Research Review Board are to assure that research and publication activities:

- Are consistent with the health goals and objectives of the Navajo Nation.
- Do not detract from, nor interfere with, the provision of health services to the Navajo people.
- Do not endanger the health of individuals or the communities.
- Address the need for informed consent of all affected individuals or their legal representatives.
- Are culturally relevant to the extent possible and are appropriate clinically, technically epidemiologically and statistically.
- Present only reasonably risks to subjects in relation to anticipated benefits, if any, to those subjects, and the importance of knowledge that reasonably may be expected to result.
- Select subjects equitably. In making this assessment the Navajo Nation Health Research Review Board shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

10. Powers of the Navajo Nation Health Research Review Board

Consistent with the requirements of this Code, the powers of the Navajo Nation Health Research Review Board shall include:

- The review and the approval or disapproval of research proposals.
- The review of manuscripts (including thesis and dissertation prior to publication)
- The negotiation of additional procedures, methodologies, and approaches to research and publication with the researchers.
- The board may request assistance from other persons with specialized knowledge in the review of any application, proposal or manuscript. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, and individuals who are mentally disabled), the Navajo Nation Health Research Review Board shall include in its reviewing body one or more individuals who have a particular concern for the welfare of these subjects.
- Subject to the approval of the Health and Social Services Committee and the requirements of this Code, the Navajo Nation Health Research Review Board shall adopt appropriate rules and procedure regarding: confidentiality of subjects; storage of specimens and other research materials; monitoring of research activities; amendments to any research proposal; financial disclosure regarding the research, volunteer payments and fees, adverse reaction of any volunteers;

applications and their contents; fees for permit and other services; and other procedures to implement this Code.

- The Board will coordinate with other appropriate boards and committees including but not limited to, other Institutional Review Boards, and the Historic Preservation Department for activities which may also be subject to the Cultural Resources Preservation Act (CMY 19-88).

11. Record Retention

The Navajo Nation Health Research Review Board shall develop and maintain an up-to-date file on all research projects, past and ongoing, approved and disapproved. Records of research projects will be maintained at least 10 years after the Navajo Nation Health Research Review Board receives the proposal or five years after publication of a paper derived from the research activity, whichever is longer. The Navajo Nation Health Research Review Board shall maintain a file of reprints of publications resulting from all research projects conducted within the territorial jurisdiction of the Navajo Nation and shall develop and maintain a bibliography and library of all known publications relating to the Navajo health issues.

12. Research permit required

Prior to undertaking any medical research within the territorial jurisdiction of the Navajo Nation, a researcher must apply for and receive from the Navajo Nation Health Research Review Board a Medical Research Permit. To receive a permit, a researcher must follow the procedures set forth in section 13, by submitting a research application.

13. Research Application

The Research Application shall be a form developed by the Navajo Nation Health Research Review Board in accordance with Section 9, but such application, at a minimum shall include: research goals, methodology, and anticipated results. The application shall also include a separate section addressing specific anticipated benefits to the study's subjects, Navajo individuals or groups of tribal members, the Navajo Nation and all other readily identifiable potential beneficiaries. The Research Application must be signed by the researcher and include a provision that the Researcher agrees to the civil jurisdiction of the Navajo Nation with respect to the research to be undertaken and any publication arising from such research.

14. Informed Consent

Before any research may be conducted on any subject, the researcher must obtain the informed consent of that prospective subject, or their parent, legal custodian or guardian, as appropriate. At a minimum this informed consent must be in writing, acknowledged by the subject, which informs the subject of the purpose of the research, any potential risks, and alternative treatments or procedures. Informed Consent may not include any exculpatory language or disclaimer of liabilities.

15. Progress Reports on Research

- Researchers shall report to the Navajo Nation Health Research Review Board the progress of their research as often and in the manner prescribed by the Navajo Nation Health Research Review Board in the research permit.

- Researchers shall promptly report any injuries to human subjects to the Navajo Nation Health Research Review Board.
- Researchers shall promptly report any unanticipated problems, which involve risk to human research subjects or others to the Navajo Nation Health Research Review Board.
- Continuing Review of Research Activity. Navajo Nation Health Research Review Board shall regularly review all research activities conducted within the territorial jurisdiction of the Navajo Nation. If, during the course of a research activity, the research conditions change, the Navajo Nation Health Research Review Board may require the researcher to amend their application consistent with the changed conditions. If the Navajo Nation Health Research Review Board determines that a research project is no longer viable because of changes in scope or effect of the research, it may rescind any research permit or otherwise limit the scope of research activities which may be conducted under the permit.

17. Publication Review Procedures

- All individuals proposing publishing covered by this Code are required to submit a manuscript to the Navajo Nation Health Research Review Board for approval, in advance of publication.
- The manuscript will be reviewed for technical content and validity, organization of content, readability, as well as assurance that they are consistent with the goals, intent and policies of this Code.

18. Permit Appeal Procedures

Researchers who are denied a research permit any request reconsideration of their application upon a showing of good cause. A request for reconsideration shall be deemed to have shown good cause if it:

- Presents a significant relevant information not previously considered by the Navajo Nation Health Research Review Board.
- Demonstrates that significant changes have occurred in factors or circumstances considered by the Navajo Nation Health Research Review Board in reaching its decision; or
- Demonstrates that the Navajo Nation Health Research Review Board failed to follow its adopted procedures in reaching its decision. A request for reconsideration must be received within 30 days after the researcher is notified of a decision. If deemed in good cause, reconsideration shall be conducted within 30 days after receipt of the appeal request.

19. Enforcement

Whenever it appears that a researcher or other person or entity has violated the provisions of this Code, the Navajo Nation Health Research Review Board on its own initiative may petition the courts of the Navajo Nation for injunction or other appropriate relief. If the court, after a hearing, finds that this Code has been violated, it may assess civil penalties up to \$5,000.00, in addition to another damages resulting from an unpermitted research activity.